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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
SCHNIZER, RICHARD A				
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
12/17/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/596,522

**Applicant(s)**

REINEKE, THERESA M.

**Examiner**

Richard Schnizer

**Art Unit**

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,6-12,14,16-20,22-31 and 33-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1,3,6-12,14,16-20,22-31 and 33-55 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB006)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ ~~Notes of Informal Patent Application~~
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 3, 6-8, 30, 31, and 33-46 drawn to methods of delivering a biologically active molecule to a cell comprising contacting the cell with a polyplex formed from an interaction between a biologically active molecule and a cellular delivery polymer that is a polyhydroxylamidoamine.

Group 2, claim(s) 1, 3, 6-8, 30, 31, and 47-50, drawn to methods of delivering a biologically active molecule to a cell comprising contacting the cell with a polyplex formed from an interaction between a biologically active molecule and a cellular delivery polymer that is a cyclodextrin-based dendritic macromolecule.

Group 3, claim(s) 1, 3, 6-8, 30, 31, and 51-53, drawn to methods of delivering a biologically active molecule to a cell comprising contacting the cell with a polyplex formed from an interaction between a biologically active molecule and a cellular delivery polymer that is a 1,3-dipolar addition polymer.

Group 4, claim(s) 1, 3, 6-8, 30, 31, 54, and 55, drawn to methods of delivering a biologically active molecule to a cell comprising contacting the cell with a polyplex formed from an interaction between a biologically active molecule and a cellular delivery polymer that is a carbohydrate-containing biodegradable polyester.

Group 5, claim(s) 9-12, 14, 16-20, and 22-29, drawn to a composition comprising a biologically active molecule and a cellular delivery polymer that is a polyhydroxylamidoamine.

Group 6, claim(s) 9-12, 14, 16-20, and 22-29, drawn a composition comprising a biologically active molecule and a cellular delivery polymer that is a cyclodextrin-based dendritic macromolecule.

Group 7, claim(s) 9-12, 14, 16-20, and 22-29, drawn to a composition comprising a biologically active molecule and a cellular delivery polymer that is a 1,3-dipolar addition polymer.

Group 8, claim(s) 9-12, 14, 16-20, and 22-29, drawn to a composition comprising a biologically active molecule and a cellular delivery polymer that is a carbohydrate-containing biodegradable polyester.

Claims 1, 3, 6-8, 30, 31 are generic to groups 1-4. Claims 9-12, 14, 16-20, and 22-29 are generic to groups 5-8. Claims will be examined to the extent that they are defined by the elected group.

The inventions listed as Groups 1-8 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature linking the different inventions is a polyplex formed from an interaction between a biologically active molecule and a cellular delivery polymer that is a polyhydroxylamidoamine, a cyclodextrin-based dendritic macromolecule, a 1,3-dipolar addition polymer, or a carbohydrate-containing biodegradable polyester. However, the prior art taught methods and compositions for delivering to cells a complex comprising a nucleic acid and a carbohydrate-containing biodegradable polyester. See for example Davis et al (US 20020044972) who taught copolymers comprising a hydrophilic region and a hydrophobic region (such as the polyester polylactide). The hydrophilic region can comprise carbohydrate targeting groups such as galactose residues. See e.g. abstract, and paragraphs 35-37, 49, and 55. Thus the technical feature that links the claimed inventions does not make a contribution over the prior art, and cannot be a special technical feature under PCT Rule 13.2. Accordingly there is a lack of unity between amongst the claimed inventions. Note that 37 CFR 1.475(b) does not allow for

grouping different statutory classes of invention (e.g. compositions and methods of use) when they do not share a special technical feature. Note also that, even if the prior art did not anticipate independent claims 1 and 12, the various inventions would still lack unity of invention because the recited Markush groups do not satisfy the requirements of the Administrative Instructions Under the PCT pertaining to Markush Practice. Specifically, the members of the Markush group do not share any common core structure and do not belong to a single recognized class of chemical compounds. For these reasons there is a lack of unity amongst the claimed invention and restriction between them is considered proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Tracy Vivlemore, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Richard Schnizer/  
Primary Examiner, Art Unit 1635